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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,540	05/10/2007	Morihiro Mitsuya	BY0042P	4472

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EXAMINER	
JAISLE, CECILIA M	

ART UNIT	PAPER NUMBER
1624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/593,540	MITSUYA ET AL.	
	Examiner	Art Unit	
	Cecilia M. Jaisle	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9 and 14-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5, 7, & 14-16* is/are rejected.

7)☒ Claim(s) *2-4,6,8 and 9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Lack of Unity

Applicants' election with traverse in the Response of Aug. 1, 2008 is acknowledged. Claims 1-5, 7-9 and 14-16 are under examination on their merits.

Applicants traverse on the ground that lack of a single general inventive concept has not been shown. However, the inventions of Groups I and II, as delineated in the Lack of Unity requirement in the Office Action of May 13, 2008, each define a separate inventive concept, because they would not be able to be rejected over one another. In addition, for all the reasons of record in the Office Action of May 13, 2008, unity is lacking between these inventions and this requirement is deemed proper.

Rejections Under 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15 and 16 are again rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for a method of treating diabetes mellitus (claim 15) or for a method of treating or preventing obesity (claim 16) with a compound of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the

invention commensurate in scope with these claims. The following reasons apply to this enablement rejection.

Substantiation of utility and its scope is required when utility is "speculative," "sufficiently unusual" or not provided. *Ex parte Jovanovics, et al.*, 211 USPQ 907, 909 (BPAI 1981). See *Hoffman v. Klaus*, 9 USPQ2d 1657 (BPAI 1988) and *Ex parte Powers*, 220 USPQ 924 (BPAI 1982) about testing needed to support *in vivo* uses.

Applicants is invited to review the Revised Interim Utility and Written Description Guidelines, 66 FR 1092-1099 (2001), emphasizing that "a claimed invention must have a specific and substantial utility." See also MPEP 2163, *et. seq*. This disclosure is insufficient to enable the method claims based only on the disclosed activity.

MPEP § 2164.01(a) states:

> A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Many factors require consideration to determine whether sufficient evidence supports a conclusion that a disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue." MPEP 2164.01(a). These factors include: (1) claim breadth; (2) nature of the invention; (3) state of the prior art; (4) level of predictability in the art; (5) amount of direction provided by the inventor; (6) presence of working examples; and (7) quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 8 USPQ2d 1400, 1404

(Fed. Cir. 1988)(reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). See also *In re Goodman* 29 USPQ2d 2010, 2013 (CAFC 1993). Application of these factors to the present application supports the determination that the present disclosure fails to satisfy the enablement requirement.

1. **Breadth of the claims:**

(a) Scope of the methods. The claims cover pharmaceutical methods using thousands of Formula (I) compounds in which X is CH.

(b) Scope of the diseases covered. The diseases construed by the claims have been described above.

Claim 15 asserts that the method treats diabetes mellitus. Management of diabetes mellitus requires maintaining normal blood glucose levels. Since diabetes may greatly increase a person's risk for heart disease, measures for controlling blood pressure and cholesterol levels are essential parts of diabetes treatment. The specification fails to teach one skilled in the art a therapeutic regimen for administration of the instant methods to achieve the desired treatment effect, what result is to be expected, or how to recognize when treatment has been achieved.

Claim 16 asserts that the method treats or prevents obesity. Obesity is determined by using weight and height to calculate "body mass index" (BMI), which correlates with an amount of body fat. An adult who has a BMI approximately between 25 and 29.9 is considered overweight. An adult who has a BMI of approximately 30 or higher is considered obese. "Prevent" means *to keep from happening,*

preclude, to anticipate, etc. The specification fails to teach one skilled in the art how to identify a host in need of such preventive treatment, a host at risk for developing obesity. The specification fails to teach one skilled in the art a therapeutic regimen for administration of the instant methods to achieve the desired preventive effect, and how long the host would need to be followed to assure that such prevention has been achieved, or to recognize when prevention has been achieved.

The specification fails to identify results of treatment or prevention with the methods of this invention in a patient or to describe how such results, especially preventive results, would be identified.

2. **Nature of the invention and predictability in the art:** The invention is directed toward medicine and is physiological in nature. The specification describes that the present compounds evidence *in vitro* GK activating action, and from that extrapolate that these compounds will treat diabetes mellitus (claim 15) and treat or prevent obesity (claim 16). It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and physiological activity is considered an unpredictable factor. *In re Fisher*, 166 USPQ 18, 24 (CCPA 1970).

Pharmacological activity in general is unpredictable. In applications involving physiological activity, such as the present:

> The first paragraph of 35 U.S.C. §112 effectively requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

Plant Genetic Systems v. DeKalb Genetics, 65 USPQ2d 1452 (CAFC 2003).

3. **Direction and Guidance:** That provided is very limited. The dosage range information is meager at best. It is generic, the same for all disorders the specification covers. No specific direction or guidance provides a regimen or dosage effective specifically for all conditions construed by the claims.

4. **State of the prior art:** The art indicates the need for undue experimentation.

Regarding a connection between GK activators and obesity and diabetes type 2, Al-Hasani, et al., Viewpoint: Molecular Interventions, Oct. 2003, Vol. 3, No. 7, pp. 367-370, report this as an area for future clinical research:

> Central administration of a GK activator such as RO-28-1675 **could**, for example, suppress neuronal circuits in the hypothalamus and the brain stem, thereby regulating appetite and energy expenditure as a consequence of constantly activated glucose sensors in the brain despite the lack of caloric intake. **In case** these compounds can be transported across the blood brain barrier and bypass the central appetite regulatory systems, weight loss **might** be achieved and future development of drugs to fight obesity as well as diabetes type 2 **might** be possible.

The present specification fails to address whether these compounds can be transported across the blood brain barrier and bypass the central appetite regulatory systems.

The ability of an agent that exhibits GK activating action shown in the specification to treat or prevent all diseases-conditions construed by the claims remains open to further study and proof.

5. **Working Examples:** Applicants have not provided competent evidence that the instantly disclosed tests are highly predictive for all uses disclosed and embraced by the claim language for all of the intended hosts.

6. **Skill of those in the art:** Al-Hasani, Johnson, Sorenson, The Center for Disease Control and Prevention, and The Office of the Surgeon General all question the ability of a single class of compounds to effectively treat and prevent the diseases/conditions construed by the claims; they confirm the need for additional research.
7. **Quantity of experimentation needed to make or use the invention.** Based on the disclosure's content, an undue burden would be placed on one skilled in the pharmaceutical arts to use the invention, since the disclosure gives the skilled artisan inadequate guidance regarding pharmaceutical use, for reasons explained above. The state of the art, as discussed herein, indicates the requirement for undue experimentation.

See MPEP 2164.01(a), discussed *supra*, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicants' invention.

Response to Applicants' Remarks of 08-01-2008

Regarding claim 15, Applicants assert, "[A]ctivators of the [glucokinase] enzyme are useful due to the combined effects of enhancing glucose uptake in liver and augmenting insulin secretion from pancreatic β-cells." However, this is not what is claimed. Applicants also assert, "Given the content of the specification, no more than routine skill is required to ... use the [method] of claim [15] in the treatment of diabetes." However, the discussion above amply calls these assertions into question.

Johnson, et al., Biochem. Soc. Transac. (2007) Vol. 35, #5, 1208-1210, discusses glucokinase activators as molecular tools for studying the physiology of insulin-secreting cells and cautiously remarks, "The development of GKAs represents a possible significant advance in diabetes therapy."

Sorenson, et al., J. Histochem. & Cytochem., Vol. 55 (6): 555-566, 2007, in discussing the immunohistochemical evidence for the presence of glucokinase in the gonadotropes and thyrotropes of the anterior pituitary gland of rat and monkey, urge the need for caution and further research:

> The presence of GK in gonadotropes and thyrotropes reported here could become a medical issue in the near future if the anticipated use of GKAs as antidiabetic drugs becomes a reality. It is likely that the drug would then be prescribed for use in large numbers of patients including also premenopausal women with type 2, and perhaps even with type 1, diabetes mellitus. In that event it will be possible and actually necessary to explore what effects GKAs may have on the physiology of gonadotropes and thyrotropes. It should also be obvious that the availability of GKAs affords an opportunity to assess the proposed glucose sensor role of GK in pituicytes experimentally in laboratory animals.

Regarding claim 16, Applicants assert:

> **Treatment and prevention of obesity** have been retained in the claims because a physician of ordinary skill is clearly able to determine which patients are is [*sic*] in need of **treatment**, can clearly determine whether **treatment** has been effective, and can clearly continue **treatment** after the initial weight loss to prevent relapse.

Note that Applicants here make no mention of their claim to **prevention of obesity**, but go on to assert that "preventive treatment" has been defined as "treatment in which the aim is to prevent the occurrence of the disease; prophylaxis." Thus Applicants admit on the record that they precisely understand the issue in regard to their claim to **prevention of obesity**. The specification fails to teach one skilled in the art how to identify a host in

need of such preventive treatment, a host at risk for developing obesity. The specification fails to teach one skilled in the art a therapeutic regimen for administration of the instant methods to achieve the desired preventive effect, and how long the host would need to be followed to assure that such prevention has been achieved, or to recognize when prevention has been achieved. Applicants assert:

> Physicians are more than capable of determining which of their patients are "in need of such **treatment**" using routine levels of skill. To allege otherwise is to fail to recognize the level of routine medical skill in the ordinarily skilled physician.

However, Applicants fail to describe on this record how a physician or any person of skill in this art would recognize a host in need of such treatment or prevention.

The Center for Disease Control and Prevention, http://www.cdc.gov/nccdphp/publications/factsheets/Prevention/obesity.htm, down-loaded 11/2/2008, emphasizes effectively preventing obesity requires lifestyle changes:

> Breastfeeding is associated with a reduced risk of obesity in children. Maternity care practices in hospitals and birthing centers can affect breastfeeding rates. Regular physical activity is an important component of weight control efforts. Proven community approaches to improve physical activity include: Community wide campaigns, Point-of-decision prompts such as signs placed by elevators and escalators that encourage people to use nearby stairs, Physical education in schools, Nonfamily social support interventions, Individually adapted health behavior change programs, Creating or improving access to places for physical activity combined with informational outreach and Changing street-scale or community-scale urban design and land use policy and practice. Reducing the time children spend watching television appears to be effective for helping to control their weight. Replacing foods of high energy density (high amount of calories per weight of food) with those of lower energy density (such as fruits and vegetables) can be an important part of a weight management strategy. Decreased consumption of sugar-sweetened beverages appears to be associated with lower body mass

> index or weight. This country can reduce obesity and other chronic diseases by improving eating habits and increasing physical activity. Increasing opportunities for healthy eating and physical activity are just some of the steps we can take to promote the health of our nation.
>
> The Office of the Surgeon General,

http://www.surgeongeneral.gov/topics/obesity/calltoaction/fact_whatcanyoudo.html, downloaded 11/3/2008, prescribes lifestyle changes to prevent obesity: Overweight and obesity are associated with heart disease, certain types of cancer, type 2 diabetes, arthritis, stroke, breathing problems and psychological disorders, e.g., depression. Physical activity contributes to weight loss, especially when combined with calorie reduction. Regular physical activity is extremely helpful to prevent overweight and obesity. Regular physical activity is very important in maintaining weight loss. In addition to weight control, physical activity helps prevent heart disease, helps control cholesterol levels and diabetes, slows bone loss associated with advancing age, lowers the risk of certain cancers and helps reduce anxiety and depression. To maintain weight, calorie intake must equal energy output; to lose weight, more calories must be use than consumed.

In regard to the issue of direction and guidance, in *Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, 86 USPQ2d 1196, 1202 (Fed. Cir. 2008), Mylan Labs. challenged the enablement of a patent to *Ortho-McNeil Pharm.* J. Rader noted three specific informative instances of the enabling teachings of the *Ortho-McNeil* patent:

> [1] …the average adult requires 30-2000 milligrams of the claimed compounds administered in two to four doses of 10-500 milligrams. [2] The specification also teaches a skilled artisan to use the claimed compounds in a manner similar to the drug phenytoin. [3] Further the specification directs the reader to a reference by L.S. Goodman, which teaches that after establishment of a low initial dose, the dosage is increased at appro-

> priate intervals as required for control of seizures or as limited by toxicity with further adjustments according to plasma drug concentrations. …

(Numbering added.) Such types of information are completely lacking in this specification. Moreover, the dosage is generic; the same for the disorders covered by both claims. The specification fails to provide the information, approvingly noted by J. Rader in *Ortho-McNeil*, for the present methods in regard to these diseases. *Ortho-McNeil* supports this rejection for lack of enablement.

Sitrick v. Dreamworks LLC, 85 USPQ2d 1826, 1830 (Fed. Cir. 2008) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable all of the embodiments. "Because the asserted claims are broad enough to cover both [embodiments], the [specification] must enable both embodiments." Here, the claims at issue cover methods of treating diabetes mellitus and methods of treating or preventing obesity and do not enable them.

Automotive Tech. Int'l. v. BMW of N. America, Inc., 84 USPQ2d 1108, 1116 (Fed. Cir. 2007) decided that a claim is not enabled when the claim covers multiple embodiments but the specification fails to enable one of the embodiments. "Thus, in order to fulfill the enablement requirement, the specification must enable the full scope of the claims that includes both [embodiments], which the specification fails to do." Here, the claims at issue cover methods of treating diabetes mellitus and methods of treating or preventing obesity and do not enable them.

Rejections Under 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

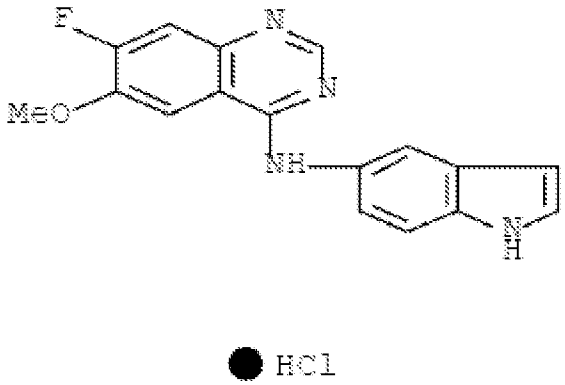
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 5, 7 and 14 are again rejected under 35 USC 103(a) over Barker, describing 4-heterocyclic-substituted-quinoazolines (col. 2, line 33 – col. 3, line 43, *inter alia*) useful as anticancer agents. Note specifically 7-fluoro-N-1H-indol-5-yl-6-methoxy-

4-quinazolinamine monohydrochloride, RN 159768-49-7 (Ex. 21),



a position isomer of the presently claimed compounds, when Y is oxygen, R1 is (3) or (6), R2 is hydrogen or fluorine, and ring A is indolyl.

One having ordinary skill in the art would have been motivated to prepare the instantly claimed compounds that are position isomers and/or alkyl homologs of the Barker compounds, because such structurally related compounds are expected to possess similar properties. It has been held that compounds that are structurally isomeric and/or homologous to prior art compounds are prima facie obvious, absent a showing of unexpected results.

> An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.

In re Payne, 203 USPQ 245, 254 (CCPA 1979). See also *In re Papesch*, 137 USPQ 43 (CCPA 1963) and *In re Dillon*, 16 USPQ2d 1897 (Fed. Cir. 1991) (discussed in MPEP § 2144) for an extensive case law review pertaining to obviousness based on close structural chemical compound similarity. See also

MPEP § 2144.08, I[II.A.4(c). Compounds that are isomers (compounds that have the same functional groups arranged is a different positional format) and/or homologs (compounds differing by the successive addition of the same chemical group, e.g., by alkyl groups), as here, are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 195 USPQ 426 (CCPA 1977). Barker establishes a *prima facie* case of obviousness for the presently claimed compounds. Absent the presentation of verifiable data establishing the unobviousness of the claimed compounds over Barker, this rejection is sound.

Response to Applicants' Remarks of 08-01-2008

Applicants assert that the Barker compounds have tyrosine kinase receptor inhibitor activity, not glucokinase activating activity as do the compounds of the present claims. However, the present compounds are obvious over as having tyrosine kinase receptor inhibitor activity and this activity has not been disproved on this record. The fact that the present compounds are described as having glucokinase activating activity does not alone establish the unobviousness of the present compounds.

Applicants' assertion that the Barker compound is missing a substituent group is in error. See the illustrated compound above. The presently claimed compounds are prima facie obvious over Barker for all the reasons advanced above.

Objectionable Claims

Claims 2-4, 6, 8 and 9 are objectionable as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Following is an examiner's statement of reasons for indication of allowable subject matter.

The subject matter of claims 2-4, 6, 8 and 9 recites substituents for the quinoazolines that are neither taught nor suggested by Barker. In addition, claims 2-4, 6, 8 and 9 are neither taught nor suggested by any of the other prior art of record, whether taken individually or in any combination.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cecilia M. Jaisle, J.D. whose telephone number is 571-272-9931. The examiner can normally be reached on Monday through Friday; 8:30 am through 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cecilia M. Jaisle

11/5/2008

/James O. Wilson/

Supervisory Patent Examiner, Art Unit 1624